Citation:

Vido L, Facchin P, Antonello I, Gobber D, Rigon F. Childhood obesity treatment: double blinded trial on dietary fibres (glucomannan) versus placebo. *Padiatr Padol.* 1993;28(5):133-6.

PubMed ID: 8247594

Study Design:

Randomized Controlled Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To evaluate the efficacy and side effects of dietary fiber (glucomannan) treatment in child obesity with specific attention to controlling body weight, lipid metabolism, biochemical parameters, endocrine function and intestinal absorption.

Inclusion Criteria:

Children under the age of 15 with primary obesity were included.

Exclusion Criteria:

Not specified.

Description of Study Protocol:

Recruitment methods not specified

Design - double blind randomized controlled trial

Blinding used - Subjects and investigators were blinded to treatment due to the capsules for fiber supplementation and placebo looked identical.

Intervention:

- During two month treatment study, all subjects followed a well balanced, normocaloric diet and were instructed to consume two capsules with two glasses of water one hour before every meal.
- Treatment group received capsules with 2 gram glucomannan (fiber) per capsule.
- Control group received identical appearing capsules without fiber.

Statistical Analysis -

Chi square and student *t* tests used for analysis of data.

Data Collection Summary:

Timing of Measurements

During 2 month treatment protocol:

- caloric intake was evaluated every 2 weeks via food journal and
- intestinal absorption, lipid metabolism, thyroid and adrenocortical function were evaluated at the beginning and end of study.

Dependent Variables

- Change in overweight
- Sense of satiety
- Side effects (variation in biochemical parameters)
- Clinical symptoms (constipation, diarrhea, abdominal pain or other abnormality)

Independent Variables

- During two month treatment study, all subjects followed a well balanced, normocaloric diet and were instructed to consume two capsules with two glasses of water one hour before every meal.
- Treatment group received capsules with 2 gram glucomannan (fiber) per capsule.
- Control group received identical appearing capsules without fiber.

Control Variables

Description of Actual Data Sample:

Initial N: 60 children (33 male, 27 female)

Attrition (final N): all participants completed study

Age: 8-14 years, average 11.2 years

Ethnicity: not specified

Other relevant demographics: not specified

Anthropometrics - Groups were similar in age, gender mix, obesity and biochemical parameters at the start of the study.

Location: Italy

Summary of Results:

Key Findings:

- Mean overweight of the drug group was decreased from 49.5% to 46.1% and that of the placebo group from 43.9% to 41.7%
- Both treatment and control groups lost a significant amount of weight during the study ($p<0.01$) but the difference between them was not significant ($p = 0.08$).
- There were no significant differences for intestinal absorption, thyroid, adrenocortical function or clinical symptoms between the treatment and control groups.
- Children treated with fiber supplements had a significant decrease of α-lipoprotein ($p<0.01$) and an increase of pre-β-lipoprotein ($p<0.01$) and triglycerides ($p<0.05$).
- Children in placebo group showed a decrease in triglycerides ($p<0.05$) and apo-β-lipoprotein ($p<0.01$).

Author Conclusion:

This study questions the efficacy of using dietary fiber supplementation in the treatment of childhood obesity and raises the question of possible atherogeneous effects.

Reviewer Comments:

Strength: Double-blind randomized study with excellent participation rate

Weakness: Unclear recruitment strategy. Study conducted in Italy and probably translated to English, only lasted 2 months. Sponsored by Dicofarm, manufacturers of the drug and placebo.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes

1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	???
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A

5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	No
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	No
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	No
6.6.	Were extra or unplanned treatments described?	No
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes

7.6.	Were other factors accounted for (measured) that could affect outcomes?	No
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	No
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	???
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	???